



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 13, 2012, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, email: [GIDAC@fda.hhs.gov](mailto:GIDAC@fda.hhs.gov), FAX: 301-847-8533, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot

always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss and provide general advice on the appropriate target populations, objectives and designs of trials intended to evaluate products for the control of hyperbilirubinemia (increased levels of bilirubin in the body) in newborn infants.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: On March 13, 2012, from 8 a.m. to 12:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 28, 2012. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 17, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled

open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 21, 2012.

Closed Presentation of Data: On March 13, 2012, from 1:15 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committee will discuss the drug development program of an investigational drug.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.  
2).

Dated: February 7, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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